IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : John Eldridge et al.

Application No.: 10/550,313 Confirmation No.: 8349

Filed : June 30, 2006

Examiner : Kelaginamane T. Hiriyanna

Group Art Unit : 1633

For : IMMUNOGENIC COMPOSITION AND METHODS

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Hon. Commissioner for Patents

P.O. Box 1450 New York, New York

Alexandria, Virginia 22313-1450 August 3, 2010

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, applicants hereby make the following documents of record in the above-identified patent application:*

U.S. PATENT DOCUMENTS

| Patent No. | <u>Issue Date</u> | Patentee(s) |
|------------|-------------------|----------------|
| 4,710,463 | 12-01-1987 | Murray |
| 5,589,466 | 12-31-1996 | Felgner et al. |
| 5,593,972 | 01-14-1997 | Weiner et al. |

^{*}A completed Form PTO/SB/08A/B listing these documents is attached hereto.

NON-PATENT LITERATURE DOCUMENTS

ALLEN et al., "Tat-vaccinated macaques do not control simian immunodeficiency virus SIVmac239 replication," Journal of Virology, 76(8):4108-4112 (2002).

BROCKMAN et al., "Herpes simplex virus vectors elicit durable immune responses in the presence of preexisting host immunity," Journal of Virology, 76(8):3678-3687 (2002).

CLEMENTS-MANN et al., "Immune responses to human immunodeficiency virus (HIV) type 1 induced by canarypox expressing HIV-1_{MN} gp120, HIV-1_{SF2} recombinant gp120, or both vaccines in seronegative adults," The Journal of Infectious Disease, 177(5):1230-1246 (1998)

DAEMEN et al., "Immunization strategy against cervical cancer involving an alphavirus vector expressing high levels of a stable fusion protein of human papillomavirus 16 E6 and E7," Gene Therapy, 9(2):85-94 (2002).

EVANS et al., "Mucosal priming of simian immunodeficiency virus-specific cytotoxic T-lymphocyte responses in rhesus macaques by the *Salmonella* type III secretion antigen delivery system," Journal of Virology, 77(4):2400-2409 (2003).

GILBERT et al., "Heterologous expression of an immunogenic pneumococcal type 3 capsular polysaccharide in *Lactococcus lactis*," Infection and Immunity, 68(6):3251-3260 (2000).

HANKE et al., "Construction and immunogenicity in a prime-boost regimen of a Semliki Forest virus-vectored experimental HIV clade A vaccine," Journal of General Virology, 84(Pt 2):361-368 (2003).

HARRINGTON et al., "Systemic, mucosal, and heterotypic immune induction in mice inoculated with Venezuelan equine encephalitis replicons expressing Norwalk virus-like particles," Journal of Virology, 76(2):730-742 (2002).

HÉCHARD et al., "Proteic boost enhances humoral response induced by DNA vaccination with the *dna*K gene of *Chlamydophila abortus* but fails to protect pregnant mice against a virulence challenge," Vet Res., 34(1):119-125 (2003).

HERMONAT et al., "Use of adeno-associated virus as a mammalian DNA cloning vector: transduction of neomycin resistance into mammalian tissue culture cells," Proc. Natl. Acad. Sci., 81(20):6466-6470 (1984).

HORTON et al., "Immunization of rhesus macaques with a DNA prime/modified vaccinia virus Ankara boost regimen induces broad simian immunodeficiency virus (SIV)-specific T-cell responses and reduces initial viral

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replication but does not prevent disease progression following challenge with pathogenic SIVmac239," Journal of Virology, 76(14):7187-7202 (2002).

LEE et al., "Novel design architecture for genetic stability of recombinant poliovirus: the manipulation of G/C contents and their distribution patterns increases the genetic stability of inserts in a poliovirus-based RPS-Vax vector system," Journal of Virology, 76(4):1649-1662 (2002).

LOEHR et al., "Priming by DNA immunization augments T-cell responses induced by modified live bovine herpesvirus vaccine," Journal of General Virology, 82(Pt 12):3035-3043 (2001).

McDERMOTT et al., "Cytotoxic T-lymphocyte escape does not always explain the transient control of simian immunodeficiency virus SIVmac239 viremia in adenovirus-boosted and DNA-primed Mamu-A*01-positive rhesus macaques," Journal of Virology, 79(24):15556-15566 (2005).

PANG et al., "Development of dengue virus replicons expressing HIV-1 gp120 and other heterologous genes: a potential future tool for dual vaccination against dengue virus and HIV," BMC Microbiology, 1:28,1-9 (2001).

QIAN et al., "Construction of a *tetR*-integrated *Salmonella enterica* serovar Typhi CVD908 strain that tightly controls expression of the major merozoite surface protein of *Plasmodium falciparum* for applications in human Vaccine production," Infection and Immunity, 70(4):2029-2038 (2002).

VINNER et al., "Immunogenicity in Mamu-A*01 rhesus macaques of a CCR5-tropic human immunodeficiency virus type 1 envelope from the primary isolate (Bx08) after synthetic DNA prime and recombinant adenovirus 5 boost," Journal of General Virology, 84(Pt 1):203-213 (2003).

WOODBERRY et al., "Prime boost vaccination strategies: CD8 T cell numbers, protection, and Th1 bias," The Journal of Immunology, 170(5):2599-2604 (2003).

XIANG et al., "Novel, chimpanzee serotype 68-based adenoviral vaccine carrier for induction of antibodies to a transgene product," Journal of Virology, 76(6):2667-2675 (2002).

REMARKS

In accordance with 37 C.F.R. § 1.98(a)(2), applicants submit herewith copies of non-patent literature documents. No copies of the listed U.S. patent documents are being submitted. 37 C.F.R. § 1.98(a)(2)(ii).

Applicants respectfully request that these documents be (1) considered by the Examiner prior to issuance of any patent from this application; and (2) printed on any patent that may issue from this application. Applicants also request that a copy of enclosed Form PTO/SB/08A/B, as considered and initialled by the Examiner, be returned with the next communication.

This supplemental IDS is being filed concurrently with a Request for Continued Examination. Accordingly, pursuant to 37 C.F.R. § 1.97(b)(4), submission of this Supplemental IDS requires no fees. However, if for any reason, a fee is due, the Director is hereby authorized payment of the fee to Deposit Account No. <u>06-1075</u>, under Order No. <u>PCFC-439-101</u>.

Respectfully submitted,

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